K053389

FEB 15 2006

B. 510(k) SUMMARY (as required by 21 CFR 807.92)

Aesculap Sterilcontainer System (Flash Indication)
20 January 2006

COMPANY: Aesculap®, Inc.
3773 Corporate Parkway
Center Valley, PA 18034
Establishment Registration Number: 2916714

CONTACT: Matthew M. Hull
610-984-9072 (phone)
610-791-6882 (fax)

TRADE NAME: Aesculap Sterilcontainer System

COMMON NAME: Sterilization Container

CLASSIFICATION NAME: Wrap, Sterilization

REGULATION NUMBER: 880.6850

PRODUCT CODE: FRG

SUBSTANTIAL EQUIVALENCE

Aesculap®, Inc. believes that the *Sterilcontainer System for Flash Sterilization* is substantially equivalent to:

Case Medical Steritite Container with Flashtite Valve (K022978)

Riley Medical Flashpak Container System (K871202)

Aesculap Sterilcontainer System (K792558)

DEVICE DESCRIPTION

The Flash compatible Aesculap Sterilcontainer is designed as a container system that will allow for sterilization and storage of other medical devices. This container is designed to be compatible for use with "Flash" prevacuum steam sterilization. The container is made from anodized aluminum and utilizes a disposable (single use) paper filter. The container system consists of a solid bottom, a perforated lid w/ filter retention plate, and disposable paper filter. Accessories such as trays, baskets, and racks can be used with it.

INDICATIONS FOR USE

The Aesculap Sterilcontainer is a reusable sterilization container system (consisting of a solid bottom, a perforated lid w/ filter retention plates, and disposable paper filters) intended to be used to enclose another medical device that is to be sterilized by a healthcare provider. It is intended to allow sterilization of the enclosed device and also maintain sterility of the enclosed device until used. This container has been validated with stainless steel lumens, hinged, and knurled instruments (stainless steel lumens of greater than 3 mm inner diameter or less than 400 mm in length). This container system is compatible for use in pre-vacuum (steam) flash sterilization. The SterilContainer System for includes accessories such as baskets, trays, and racks.

TECHNOLIGICAL CHARACTERISTICS(compared to predicate(s))

This is exactly the same Aesculap sterilization container system that was cleared for use in prevacuum and gravity steam in 510(k) # K792558. The Aesculap container and the Case Medical container are both made from anodized aluminum while the Flashpak is made from plastic. All of these container systems are compatible with wire mesh baskets and other instrument organizer inserts. All three container systems are offered in a similar range of sizes. All three devices have gasketed lids that latch and offer tamper-evident features.

PERFORMANCE DATA

The Aesculap Sterilcontainer system was fully validated for the additional indication of flash sterilization in a prevacuum steam cycle. This validation was conducted in accordance with FDA guidance and available AAMI standards by a qualified testing laboratory. Additionally comparative testing was done on a predicate device to demonstrate similar performance characteristics and prove efficacy of the Aesculap container.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 15 2006

Mr. Matthew M. Hull
Regulatory Affairs Manager
Aesculap, Incorporated
3773 Corporate Parkway
Center Valley, Pennsylvania 18034

Re: K053389
Trade/Device Name: Aesculap Sterilcontainer System for Flash
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: II
Product Code: FRG
Dated: February 3, 2006
Received: February 6, 2006

Dear Mr. Hull:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

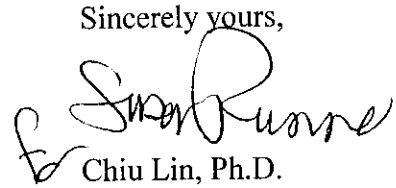
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

A. INDICATIONS FOR USE STATEMENT

510(k) Number: K053389

Device Name: ***Aesculap Sterilcontainer System for Flash***

Indications for Use:

The Aesculap Sterilcontainer is a reusable sterilization container system (consisting of a solid bottom, a perforated lid w/ filter retention plates, and disposable paper filters) intended to be used to enclose another medical device that is to be sterilized by a healthcare provider. It is intended to allow sterilization of the enclosed device and also maintain sterility of the enclosed device until used. This container has been validated with stainless steel lumens, hinged, and knurled instruments (stainless steel lumens of greater than 3 mm inner diameter or less than 400 mm in length). This container system is compatible for use in pre-vacuum (steam) flash sterilization. The SterilContainer System for includes accessories such as baskets, trays, and racks.

The following containers (lids & bottoms) were validated for pre-vacuum Flash sterilization:

Full Size: Lid JK489/ Bottoms JK440, JK441, JK442, and JK444
Three-Quarter Size: Lid JK789/ Bottoms JK740, JK741, and JK742
Half Size: Lid JK389/ Bottoms JK339, JK340, JK341, JK342, and JK344
Mini Containers: Lid JK174/ Bottoms JK187 and JK188

Prescription Use _____ and/or Over-the-Counter Use X _____

(per 21 CFR 801 Subpart D) (per 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Sheila A. Murphy 2/10/06

[illegible] Surgery, General Hospital,
[illegible] Dental Devices

[illegible] K053389